REMARKS

Claims 29-34 and 55-68 are pending and are the subject of the office action.

The pending claims were previously indicated to be in condition for allowance but were suspended due to potential interference. In the present office action the suspension and indication of allowability have been withdrawn in view of new rejections, addressed below.

Double Patenting Rejections

Claims 55-62 and 67-68 were provisionally rejected as being unpatentable over claims 55-61, 64-75, and 78-81 of co-pending application no. 10/242,383.

Applicants wish to advise that application no. 10/242,383 is no longer pending, and therefore it is believed this provisional rejection should be withdrawn.

Section 102 Rejections

Claims 55-62 and 67-68 were rejected under Section 102(e) as being anticipated by Wei et al., US Patent 6,261,801 ("the '801 patent"). This rejection has been re-introduced even though it was initially withdrawn in the office action mailed June 3, 2003. Applicants traversed the rejection previously, and Applicants maintain their traversal on grounds that the '801 patent does not anticipate under Section 102(e).

The '801 patent claims priority to provisional application no. 60/054,885 filed August 7, 1997 and to provisional application no. 60/035,496 filed January 14, 1997[1]. The disclosure provided by Wei et al. changed markedly every time their application was re-filed.

As the present application has a priority filing date of June 18, 1997, before the August 7, 1997 filing date of Wei et al.'s 60/054,885 application, the only disclosure which may be considered for purposes of Section 102(e) is that which appears in the January 14, 1997 60/035,496

[1]Both of Wei et al.'s provisional applications have previously been cited in Applicants' Information Disclosure Statement filed for the present application.

application filed by Wei et al.

Wei et al.'s 60/035,496 application fails to provide an enabling disclosure for the claims presented in the instant application. While the 60/035,496 application provides certain sequence information for the molecule referred to as TNFR-5, there is no teaching or suggestion in that application as to what TNFR-5 is or what function(s) or activity(s) that TNFR-5 has. The 60/035,496 application is silent with regard to any characterization of the TNFR-5 molecule. The fact that Wei et al. did not recognize a function or activity of TNFR-5 is demonstrated by the text on page 51, lines 5-18, of the 60/035,496 application wherein Wei et al. suggest the molecule could be employed in connection with diseases as diverse as cancer, autoimmune disorders, AIDS, stroke and toxin-induced liver disease, etc.

Wei et al.'s attempt to impute a function or activity to the TNFR-5 molecule in the 60/035,496 application even fails on the basis of their very own admissions made in the application at pages 4, lines 1-3 and 50, lines 21-24, respectively:

> The effects of TNF family ligands and TNF family receptors are varied and influence numerous functions, both normal and abnormal, in the biological processes of the mammalian system.
>
> The Tumor Necrosis Factor (TNF) family ligands are know to be among the most pleiotropic cytokines, inducing a large number of cellular responses, including cytotoxicity, anti-viral activity, immunoregulatory activities, and the transcriptional regulation of several genes...

Such statements clearly teach one skilled in the art that uncertainty and unexpectedness surrounds such molecules until the molecules are actually experimentally characterized.

It is asserted in the office action that the 60/035,496 application established that soluble forms of TNFR-5 can function as antagonists, and antagonists are capable of inhibiting apoptosis. Applicants respectfully disagree. As discussed above, the 60/035,496 application provides no experimental characterization of an activity or function of TNFR-5, and in the absence of any knowledge of what type(a) of activity or function TNFR-5 is involved in, reference to an "antagonist" of that receptor

likewise has no meaning. If the skilled artisan does not know or understand the activity or function of an orphan receptor, the skilled artisan likewise does not know or understand the activity or function of an "antagonist" of that receptor. The 60/035,496 application does not describe any experimental data revealing that TNFR-5 is involved in apoptosis, so it is not clear how one could generally make the assertion that "antagonists are capable of inhibiting apoptosis."

As pointed out in Applicants' previous response, the teaching by Wei et al. that the TNFR-5 molecule binds TRAIL (or Apo-2 ligand) was added to the disclosure in the August 7, 1997 60/054,885 application, AFTER the priority filing date of the instant application. Wei et al. do not teach or suggest any such binding property in their January 14, 1997 60/035,496 application, and so TNFR-5's activity or function cannot be established on the basis of identifying a cognate ligand which binds to TNFR-5.

It is also asserted in the office action that the 60/035,496 application discloses administration of an antagonist to reduce selective killing of CD4 T-lymphocytes in HIV+ individuals. It is submitted that such prophetic disclosure is furthermore non-enabling in view that those skilled in the art understand that HIV is a complex and unpredictable therapeutic field. While the Examiner has made reference to the Miura et al. article to somehow provide post-published evidence in support of a purported activity of a TNFR-5 antagonist, it is submitted that the disclosure must be enabling as of its filing date. The prophetic and speculative disclosure of the 60/035,496 application clearly does not provide an adequate disclosure as of its January 14, 1997 filing date, and use of a post-published journal article to cure the deficiencies of that disclosure as of its filing date should not be permitted.

For at least these reasons, the 60/035,496 application fails to provide an enabling disclosure for either TNFR-5 molecules or antibodies directed to TNFR-5 and cannot be applied for purposes of anticipation

under Section 102(e) against the claims presented in the instant application.

Respectfully submitted,

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